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DATE MAILED: 12/24/2003

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,696	12/05/2001	Daniel F. Bischof	F-5801	7252
7590 12/24/2003			EXAMINER	
Michael C. Mayo Baxter Healthcare Corporation			SAUCIER, SANDRA E	
Fenwal Division, RLP-30			ART UNIT	PAPER NUMBER
P.O. Box 490 - Route 120 & Wilson Road			1651	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)		
10/004,696	BISCHOF ET AL.		
Examiner	Art Unit		
Sandra Saucier	1651		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

- THE MAILING DATE OF THIS COMMUNICATION.

afte - If th - If No - Fail - Any	O period for reply is specified above, the maximum	mmunication. (30) days, a reply within the stat statutory period will apply and w ply will, by statute, cause the app s after the mailling date of this co	tutory minimum of thirty (30) days will be considered timely. ### This is the communication to be communication. #### This is the communication of the communication of the communication.				
Status							
1)[Responsive to communication(s) f	iled on <u>08 September 2</u>	<u>2003</u> .				
2a)⊠	This action is FINAL.	2b) This action is no	on-final.				
3)□			for formal matters, prosecution as to the merits is alwayle, 1935 C.D. 11, 453 O.G. 213.				
Disposit	tion of Claims						
4)🛛	Claim(s) 1-5 and 7-28 is/are pending in the application.						
	4a) Of the above claim(s) 11-24 is/	are withdrawn from cor	nsideration.				
5)[Claim(s) is/are allowed.						
6)⊠)⊠ Claim(s) <u>1-5,7-10 and 25-28</u> is/are rejected.						
	Claim(s) is/are objected to.						
8)[Claim(s) are subject to rest	riction and/or election r	equirement.				
Applicat	ion Papers						
9)[The specification is objected to by	the Examiner.					
10)🖂	☐ The drawing(s) filed on 05 December 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
,	Applicant may not request that any ob	jection to the drawing(s) t	pe held in abeyance. See 37 CFR 1.85(a).				
	Replacement drawing sheet(s) includi-	ng the correction is requir	ed if the drawing(s) is objected to. See 37 CFR 1.121(d).				
11)	The oath or declaration is objected	to by the Examiner. No	ote the attached Office Action or form PTO-152.				
Priority :	under 35 U.S.C. §§ 119 and 120						
12)	Acknowledgment is made of a clai	m for foreign priority ur	ider 35 U.S.C. § 119(a)-(d) or (f).				
	☐ All b)☐ Some * c)☐ None of	:					
	1. Certified copies of the priorit						
•	2. Certified copies of the priorit		ents have been received in this National Stage				
	application from the Internat						
	See the attached detailed Office act	ion for a list of the certi	fied copies not received.				
			nder 35 U.S.C. § 119(e) (to a provisional application)				
	since a specific reference was included. 37 CFR 1.78.	led in the first sentence	of the specification or in an Application Data Sheet.				
	a) ☐ The translation of the foreign la	anguage provisional ar	plication has been received.				
14) 🗌 /	Acknowledgment is made of a claim	for domestic priority u	nder 35 U.S.C. §§ 120 and/or 121 since a specific				
r	eference was included in the first se	entence of the specifica	tion or in an Application Data Sheet. 37 CFR 1.78.				
Attachmer	nt(s)						
	ce of References Cited (PTO-892)		4) Interview Summary (PTO-413) Paper No(s)				
	Daviden Data of Demoiles Berjand	(DTO 040)	E) Thelian of Informal Datast Application (DTO 452)				

2) \(\sum \) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) \(\overline{\text{N}} \) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \(\frac{9/03, 4/03}{2} \).

5) Notice of Informal Patent Application (PTO-152)
6) Other:

DETAILED ACTION

Claims 1-5, 7-28 are pending. Claims 1-5, 7-10, 25-28 are considered on the merits. Claims 11-24 are withdrawn from consideration as being drawn to a non-elected invention.

This application contains claims drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Specification

The amendment filed 9/8/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: 22–35 mM sodium phosphate.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Claims 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 25, the order of the steps is not clear. Does the method require providing three more containers? Is the liquid storage medium the same medium as in claim 1?

Claim Rejections - 35 USC § 102

Claims 1, 3-5, 7-10, 25-28 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 6,544,727 [IDS]

Application/Control Number: 10/004,696

Art Unit: 1651

The claims are directed to a method for preparing a blood product comprising:

providing a container system with at least two containers, an interim container and a synthetic medium container, connected to each other, providing a source container with a blood component or blood, connecting the source container to the interim container, transferring the blood or blood component to the interim container, combining the blood or blood component with synthetic medium in the interim container.

The references are relied upon as explained below.

See Figures 49 and 50 and example 42. Three containers are connected. One container contains platelets and plasma which are transferred to an empty platelet storage container, another container contains medium which is also transferred to the platelet storage container. Further, the disclosed method includes concentrating blood components and transferring supernatant (plasma) to PRP to achieve a pre-selected ratio.

Claim Rejections - 35 USC § 103

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,544,727 [IDS].

The claim is directed to the method of claim 1 where the blood component substantially comprises red cells.

The substitution of red cells for platelets in the method of US 6,544,727 would have been obvious because '727 states in the "Summary of Invention" that the application provides method of using...compounds to inactivate pathogens ...particularly in blood products in synthetic media. Blood products include red cells. Thus, the suggestion to apply the methods disclosed in the examples is found in the generic disclosure.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 9/8/03 prompted the new grounds of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308–4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308–1084. Status inquiries must be directed to the Customer Service Desk at (703) 308–0197 or (703)–308–0198. The number of the Fax Center for the faxing of official papers is (703) 872–9306.

Sandra Saucier Primary Examiner Art Unit 1651 December 19, 2003